

**Opening Remarks
Ed R. B. McCabe, Ph.D., M.D.
SACGHS Chair**

DR. McCABE: Good morning, everyone, and welcome to the third meeting of the Secretary's Advisory Committee on Genetics, Health, and Society.

The public was made aware of this meeting through notices in the Federal Register, as well as announcements on the SACGHS website and listserv.

First I'd like to take note of two new ex officio appointments to the committee. We're extremely pleased to welcome Mr. Matthew Daynard, senior attorney for the Federal Trade Commission. Mr. Daynard briefed us in October about the FTC's mission; and also Dr. Ellen Fox, director of the National Center for Ethics at the Department of Veterans Affairs. Thank you both for participating.

We're extremely pleased that your agencies regard the work of SACGHS as important and relevant to their missions. As with all of our ex officio members, we very much appreciate the time and effort that you make to participate in the work of the committee and the expertise and perspective that you all bring to our deliberations.

Before I review today's agenda, I'd like to remind everyone that at the end of the October meeting, the committee decided that it was important to engage in a systematic process to determine the priority issues that should be the focus of our work during the next year. An inter-meeting task force was formed to guide the issue identification process and help plan this meeting.

During the past four months, the task force has been hard at work on this important project. I'd like to take this opportunity to thank the members of the task force for your efforts on the committee's behalf. Emily Winn-Deen, who chaired the group; Cindy Berry; Barbara Harrison; Debra Leonard; Reed Tuckson; and Hunt Willard, all members of the task force.

In a moment we will hear more about the activities of the task force from Emily Winn-Deen.

I also want to say a word about the 12 issue briefs in Tab 4 of your briefing books. They were prepared by SACGHS staff under the direction of the task force. The briefs have provided us with precise background information about the issues, given us deeper understanding of their policy implications, and helped prepare us for our deliberations. I'd like to thank the SACGHS staff for your hard work and dedication in preparing the briefs. Our thanks and compliments especially to the principal authors, Amanda Sarata, Fay Shamanski, Suzanne Goodwin, and Krista Crider. Of course, since Sarah prepared these remarks for me, she did not give herself credit for having supervised all of that work, so thank you because we know how much, Sarah, you put into this as well.

Actually, Hunt Willard and I were commenting that before the session this morning, that we think these are such excellent documents at framing these issues that we really think that there ought to be an exploration of publication in some forum to get this work out so even more of the public could see this.

*SACGHS March 2004 Meeting
Meeting Transcript*

The primary goals of this meeting are, one to identify the top one to three issues that will be our focus for the coming year; two, to develop a work plan, and three, to begin deliberations on the first issue. The first half of today's agenda will be devoted to hearing about the work of the task force and advancing our priority-setting process. In order to organize the forthcoming discussion and engage the committee's current views on the prioritization of issues, we will take a straw vote before today's first break. Then, with the benefit of today's discussion, we will take a second straw vote at the end of the day. You'll find in your table folders two ballots to use for these straw votes. These are in the white briefing folders, this one, so that you can find them and be prepared for those straw votes.

In the afternoon we will hear a series of presentations and will hold a roundtable discussion on coverage and reimbursement of genetic technologies and services. Questions about coverage and reimbursement were raised in the October meeting, and a number of members suggested that an in-depth briefing might be in order. In addition, coverage and reimbursement is one of the 12 priority issues under consideration, and during the inter-meeting process it was ranked among the top three issues.

This afternoon's session will explore public and private health insurance coverage and payment policies for genetic technologies, the perspectives of service providers and the financing and economic considerations with respect to these technologies.

Tomorrow, after we make our final determinations about the top three priority issues, we will develop a long-range work plan for accomplishing the three projects. Then we will begin deliberations on the top priority issues. We hope to make enough progress on the first issue to be able to outline preliminary recommendations to the Secretary.

Let me also point out that we have public comment sessions each day. We will hear testimony immediately following lunch today and first thing tomorrow morning. We have a number of individuals, five, who have registered to address us. If there are others here who wish to provide comments, please inform the individuals at the registration desk so that you can get onto the list.

I'll now turn to Sarah Carr for an important reminder about the conflict of interest rules.

Sarah?

MR. CARR: Thank you, Ed.

Being a member of this committee makes you a special government employee -- I'm speaking to the members of the committee now -- and thereby subject to rules of conduct that apply to government employees. The rules and regulations are explained in a report called "Standards of Ethical Conduct for Employees of the Executive Branch." This is a report that each of you received when you were appointed to the committee. I'm just going to review one of the rules in that document.

Before every meeting, you provide us with information about your personal, professional, and financial interests, information that we use to determine whether you have any real, potential or apparent conflicts of interest that could compromise your ability to be objective in giving advice during committee meetings. We waive conflicts of interest for general matters because we believe your ability to be objective will not be affected by your interest in such matters; but we also rely to a great degree on you to be attentive during our meeting to the possibility that an issue

*SACGHS March 2004 Meeting
Meeting Transcript*

will arise that could affect or appear to affect your interest in a specific way.

In addition, we have provided each of you with a list of your financial interests and covered relationships that would pose a conflict for you if they became a focal point of committee deliberations. If this happens, we ask that you recuse yourself from the meeting and leave the room.

If you have any questions about these rules and your interests, our committee management officers can help address those questions. David Alperin and Claire Harris are this committee's committee management officers, and David at least is here today, and I think Claire will be here later.

Thank you.

DR. WILLARD: Ed, could I ask Sarah a question on that issue?

Could you address explicitly how we are supposed to behave in discussing issues in which either we or colleagues at our institutions either have grant applications in to the federal government or are anticipating those applications? So as we prioritize issues, there is at least an indirect potential for conflict of interest in leaning the deck in areas where we have our own expertise or institutional expertise.

MS. CARR: I would still say those are general matters. The discussions that we have about those things, and if the committee decided to make something a priority where you are doing research -- let's say pharmacogenomics -- the fact that the committee made that a high priority isn't going to, in my estimation -- and we can talk to our committee management officers about this more specifically. But in my estimation, you would not be favoring yourself in any specific way. So as long as the discussions are about general issues and you will not benefit specifically from decisions of the committee, I think you'll be okay.

But if you ever have any doubt about it, and I know what you're trying to do is get clarification, but if you have any doubt, just come up to me and we'll try to take care of it. I think if you ever have a doubt, the best thing to do is to leave.

David, go ahead.

MR. ALPERIN: Hi. I'm David Alperin with NCI's committee management office. We do all your ethics clearance.

In relation to your question, the specifics of ethics clearance is for you as an individual and the holdings that you have that you would receive a direct benefit if you had insider knowledge of a decision to be made by this committee. If your colleagues have grant applications, that is not a specific issue for you. That is an issue for your institution, and you are not here representing your institution. You are in here for your specific professional expertise. So I don't feel that anything related to a colleague that may or may not have a grant application in process or a grant application for your institution would be an issue that would require you as an individual to recuse yourself from the discussions.

Does that help?

DR. WILLARD: Sort of. I mean, I guess the issue, without hammering this too deeply, is if I

*SACGHS March 2004 Meeting
Meeting Transcript*

had a grant application in on genetic non-discrimination, it seems to me to be in my best interest to have this committee decide that genetic non-discrimination is one of the big issues that we want to have the Secretary put his weight behind. So would you consider that to be a direct conflict or not a direct conflict?

MR. ALPERIN: I would say that that is not a direct conflict. However, it may be a potential conflict. If this becomes an issue of a very focussed discussion, it would probably be the best course of action for you to recuse yourself from that specific section of the discussion.

DR. WILLARD: Okay. Thank you.

DR. McCABE: The other thing that I will remind everyone is that as a special federal employee, you should not engage in any lobbying of the government agencies or on the Hill while you're here on this visit. Similarly, I think it would not be wise to be involved in any discussions with any companies or relevant to any private holdings that one might have involvement with.

I think that the discussion that we just had is that if you feel uncomfortable about it, then there's a perception of a conflict of interest and it's probably best to recuse yourself at that point, since it's frequently perception as well as reality.

Thank you for that discussion and for pursuing it further.

Emily Winn-Deen will now review the process and outcome of the inter-meeting priority-setting project.

Emily, let me thank you very much for chairing the task force. I know how much time and effort you put into advancing this during the interim and in the issue identification process and planning and organizing the meeting.

Let me also remind the committee that as Emily reviews the process and issues, you should be thinking again about your rankings. We will take a straw vote after Emily's presentation before the break so that Sarah and her staff can have time to tally that vote over the break.

Thank you.

Emily?